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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,115	11/01/2003	Warren L. Starkebaum	P0009903.01	8923

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EXAMINER	
BERHANU, ETSUB D	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,115	STARKEBAUM, WARREN L.	
	Examiner	Art Unit	
	Etsub D. Berhanu	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 6, 8, 9, 11, 12 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Crothall'727 (USPN 6049,727).

Crothall'727 discloses a method for monitoring stomach activity of a patient, the method comprising: implanting an implantable medical device comprising a memory (col. 23, lines 60-62) and a processor (col. 8, lines 34-37) in a patient, sensing a physiological parameter of the patient that changes as a function of activity of a stomach of the patient, supplying sensed physiological parameters to the implanted medical device to be stored in the memory and tracked by the processor, measuring through the processor a characteristic of the physiological parameter and generating by the processor of the implanted medical device a communication to the patient as a function of the sensed physiological parameter, wherein the sensed physiological parameter is a blood glucose concentration and generating the communication comprises transmitting a wireless communication to an external module (col. 6, lines 12-40 and col. 7, line 52 – col. 8, line 43).

Figure 1 of Crothall'727 discloses a system, the system comprising: an implantable sensor (10), an implantable programmable processor (18) comprising a memory with instructions to store data

associated with a blood glucose concentration measurement and to compare the blood glucose concentration to a threshold and generate a communication to a patient as a function of a measured blood glucose concentration wherein the communication notifies the patient that a change has occurred in the activity of the stomach, and a communication module (24 and 26) to wirelessly transmit the communication to an external module (see description of Figure 1 in col. 7, line 52 – col. 8, line 43 and col. 23, line 55 – col. 24, line 23). Figure 1 of Crothall'727 further discloses a therapy delivery means (23) wherein the processing means is configured to generate a signal to the therapy delivery means to cause therapy to be delivered to the patient a function of the blood glucose measurement (col. 8, lines 7-11).

3. Claims 8, 9 and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Clegg et al.'808 (previously cited).

See rejection set forth in paragraph 5 of the Office Action mailed out on 17 February 2006.

4. Claims 1-6, 8, 9, 15, 16 and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourgeois'994 (previously cited).

Bourgeois'994 discloses a method for monitoring stomach activity of a patient, the method comprising: implanting an implantable medical device comprising a memory (col. 6, lines 11-13) and a processor (Figure 4, processor 46) in a patient (col. 3, lines 4-5), sensing a physiological parameter of the patient that changes as a function of activity of a stomach of the patient, supplying sensed physiological parameters to the implanted medical device to be stored in the memory and tracked by the processor, measuring through the processor a characteristic of the physiological parameter and generating by the processor of the implanted medical device a communication to the patient as a function of the sensed physiological parameter, wherein the sensed physiological parameter is an amplitude of a pulse corresponding to gastric electrical activity (col. 7, lines 15-19) and a transabdominal impedance (col. 11, lines 29-30) and generating the communication comprises transmitting a wireless communication to an

external module (col. 2, lines 3-30, col. 6, line 43 – col. 7, line 21 and col. 11, lines 27-28). Bourgeois'994 further discloses a method of using two sensors to detect normal peristaltic contractions, whereby one sensor measures low frequency gastrointestinal electrical activity and a second sensor senses intrinsic gastrointestinal electrical activity, wherein the second sensor only senses after slow waves have been sensed by the first sensor (col. 2, lines 10-21).

Bourgeois'994 also discloses a system, the system comprising: an implantable sensor (Figure 1, system 1) with a programmable processor (Figure 4, processor 46) comprising a memory with programmed instructions to store data associated with a gastric electrical activity measurement and to compare the measurement to a threshold (col. 4, lines 42-48 and col. 10, line 66 – col. 11, line 1)) and generate a communication to a patient as a function of a sensed physiological parameter and notify the patient that a change has occurred in the activity of the stomach (col. 6, line 50 – col. 7, line 21), a wireless communication module (Figure 4, element 49), electrical sensors that sense gastric electrical activity and transabdominal impedance (col. 2, lines 10-21), and therapy delivery means (electrical stimulation to the gastrointestinal tract if normal peristaltic contractions are not detected) wherein the processing means is further configured to generate a signal to the therapy delivery means to be delivered to the patient as a function of the gastric electrical activity measurement (col. 2, lines 27-30, col. 3, lines 19-21 and Figure 7 and description thereof). Regarding claim 23, it is noted that the processor (46) inherently has a computer-readable medium comprising instructions to cause the processor to carry out the method as discussed above.

5. Claims 1-4, 6-12, 15 and 18-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Houben et al.'542 (USPN 6,572,542)

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any

invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Houben et al.'542 discloses a method for monitoring stomach activity of a patient, the method comprising: implanting an implantable medical device comprising a memory (col. 15, lines 51-53) and a programmable processor (Figure 7, element 34) in a patient, sensing a physiological parameter of the patient that changes as a function of activity of a stomach of the patient, supplying sensed physiological parameters to the implanted medical device to be stored in the memory and tracked by the processor, measuring through the processor a characteristic of the physiological parameter and generating by the processor of the implanted medical device a communication to the patient as a function of the sensed physiological parameter, wherein the sensed physiological parameter is a blood glucose concentration and insulin concentration and generating the communication comprises transmitting a wireless communication to an external module, wherein generating the communication comprises activating an implanted alert module (col. 12, line 46 – col. 13, line 14, line 3).

Figure 7 of Houben et al.'542 further discloses a system, the system comprising: a sensor to sense a physiological parameter of a patient that changes as a function of activity of a stomach of a patient, a programmable processor (34) comprising a memory with programmed instructions to generate a communication to a patient as a function of the sensed physiological parameter and notify the patient that a change has occurred in the activity of the stomach, a communication module (42) to wirelessly transmit the communication to an external module (41), an implanted alert module (25 and see col. 13, lines 45-50), chemical sensor (45), electrical sensors (21 and 40) and therapy delivery means (47) wherein the processor is configured to generate a signal to the therapy delivery means to cause therapy to be delivered to the patient as a function of the measured blood glucose or insulin concentration (see description of Figure 7). It is noted that in being able to detect a hypo or hyperglycemic event in a patient, the system of Houben et al.'542 must compare the measured blood glucose or insulin concentration to a threshold

amount in order to assess whether the blood glucose or insulin concentration is either too high or too low, and therefore, the processor of the system (Houben et al.'542 indicates that the processor is the control of the system in col. 5, lines 65-67) is inherently configured to compare the measured concentrations to a threshold value.

Response to Arguments

6. Applicant's arguments with respect to claims 1-7, 10 and 18-23 have been considered but are moot in view of the new ground(s) of rejection.

7. Regarding claims 8, 9 and 11-17, Applicant's arguments filed 17 August 2006 have been fully considered but they are not persuasive. Applicant argues on page 8 of the Remarks that Clegg et al.'808 fails to disclose a programmable processor or an implantable medical device. Examiner notes that the subject matter disclosed in claims 8, 9 and 11-17 do not recite the limitation of an implantable medical device or an implantable processor. The processor of Clegg et al.'808 is capable of being programmed (col. 4, lines 28-30), and in being able to generate a communication to the patient (col. 3, line 68 – col. 4, line 2), inherently contains a memory comprising instructions to carry out the method of generating a communication to the patient. For these reasons, the rejection of claims 8, 9 and 11-17 are upheld. Regarding claim 18, it is noted that the processor of Clegg et al.'808 is capable of being implanted and further, Clegg et al.'808 discloses that the devices used to measure the physiological parameters, including the processor, are capable of being inserted (implanted) within the gastrointestinal tract (col. 2, lines 64-68).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lord et al.'186 (USPN 5,569,186) and Sun et al.'860 (USPN 5,995,860) both disclose implantable

glucose sensors comprising an implantable processor and means to control an implanted insulin infusion pump.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB

ERIC F. WINAKUR
PRIMARY EXAMINER